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encompasses 50% or more of the locus of pain, and wherein the administration is is not at the locus of pain, thereby relieving the pain for at least one month.

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- 24. The method of claim 23 wherein the patient has at least eleven loci of pain.
- 25. The method of claim 23 wherein the locus of pain and the peripheral location are located within a dermatome.
- 26. The method of claim 23 wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F, and G.
- 27. The method of claim 23 wherein the botulinum toxin is a botulinum toxin type A.
- 28. The method of claim 23 wherein the location of administration and the locus locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 29. The method of claim 23 wherein the botulinum toxin is administered with a needle.
- 30. The method of claim 23 wherein the botulinum toxin is administered by needleless injection.
- 31. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain which is at a fibromyalgia tender point, and wherein the local administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.
- 32. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient, wherein the patient has a locus of pain which is at a fibromyalgia tender point, wherein the dermatome encompasses 50% or more of the locus of pain, and wherein the administration is not at the locus of pain, thereby relieving the pain for at least one month.

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File: USPT

Sep 23, 2003

US-PAT-NO: 6623742

DOCUMENT-IDENTIFIER: US 6623742 B2

TITLE: Methods for treating fibromyalgia

DATE-ISSUED: September 23, 2003

INVENTOR - INFORMATION:

NAME CITY

STATE ZIP CODE

COUNTRY

Voet; Martin A.

San Juan Capistrano

CA

US-CL-CURRENT: 424/236.1; 424/247.1, 435/71.3, 514/12, 514/2, 530/344, 530/350

CLAIMS:

What is claimed is:

- 1. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient afflicted with fibromyalgia, wherein the peripheral location is not a locus of pain, and wherein the locus of pain and the site of administration are located within a same dermatome, thereby relieving a fibromyalgia pain for at least one month.
- 2. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is not in the head of the patient.
- 3. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
- 4. The method of claim 1 wherein the peripheral location is in a cranial area or a facial area of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
- 5. The method of claim 1 wherein the <u>botulinum toxin</u> is selected from the group group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F, and G.
- 6. The method of claim 1 wherein the botulinum toxin is a botulinum toxin type A.
- 7. The method of claim 1 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 8. The method of claim 1 wherein the botulinum toxin is administered with a needle.
- 9. The method of claim 1 wherein the botulinum toxin is administered by

needleless injection.

- 10. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, and wherein the peripheral location is not at the locus of pain, and the locus of pain and the site of administration are located within a same dermatome, thereby relieving the pain for at least one month.
- 11. The method of claim 10 wherein the patient has at least eleven loci of pain.
- 12. The method of claim 10 wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F, and G.
- 13. The method of claim 10 wherein the botulinum toxin is a botulinum toxin type A.
- 14. The method of claim 10 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 15. The method of claim 10 wherein the botulinum toxin is administered with a needle.
- 16. The method of claim 10 wherein the <u>botulinum toxin</u> is administered by needleless injection.
- 17. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain, wherein the administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.
- 18. The method of claim 17 wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F, and G.
- 19. The method of claim 17 wherein the botulinum toxin is a botulinum toxin type A.
- 20. The method of claim 17 wherein the location of administration and the locus locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 21. The method of claim 17 wherein the <u>botulinum toxin</u> is administered with a needle.
- 22. The method of claim 17 wherein the <u>botulinum toxin</u> is administered by needleless injection.
- 23. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a dermatome of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, wherein the dermatome

encompasses 50% or more of the locus of pain, and wherein the administration is is not at the locus of pain, thereby relieving the pain for at least one month. month.

- 24. The method of claim 23 wherein the patient has at least eleven loci of pain.
- 25. The method of claim 23 wherein the locus of pain and the peripheral location are located within a dermatome.
- 26. The method of claim 23 wherein the botulinum toxin is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, and G.
- 27. The method of claim 23 wherein the $\underline{botulinum\ toxin}\ is\ a\ botulinum\ toxin}$ type A.
- 28. The method of claim 23 wherein the location of administration and the locus locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 29. The method of claim 23 wherein the $\underline{botulinum\ toxin}$ is administered with a needle.
- 30. The method of claim 23 wherein the botulinum toxin is administered by needleless injection.
- 31. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain which is at a fibromyalgia tender point, and wherein the local administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.
- 32. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient, wherein the patient has a locus of pain which is at a fibromyalgia tender point, wherein the dermatome encompasses 50% or more of the locus of pain, and wherein the administration is not at the locus of pain, thereby relieving the pain for at least one month.

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	L2	(botulinum or botulism or neurotoxin or neuro-toxin or toxin).ti,ab,clm.	13773
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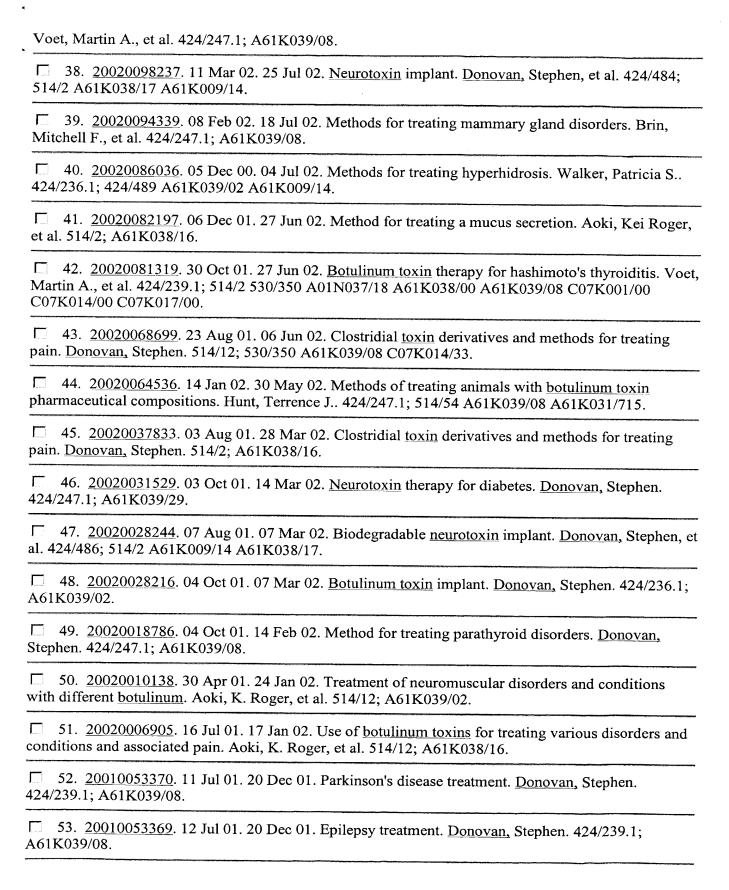
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File: PGPB

Jul 1, 2004

PGPUB-DOCUMENT-NUMBER: 20040126397

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TITLE: Use of the neurotoxic component of a <u>botulinum toxin</u> for treating various disorders and conditions and associated pain

PUBLICATION-DATE: July 1, 2004

INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
Aoki, Kei Roger	Coto De Caza	CA	US	
Grayston, Michael W.	Irvine	CA	US	
Carlson, Steven R.	San Mateo	CA	US	
Leon, Judith M.	San Juan Capistrano	CA	us	

US-CL-CURRENT: 424/239.1

CLAIMS:

What is claimed is:

- 1. A method for treating strabismus, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a <u>botulinum toxin</u> substantially free of a <u>botulinum toxin</u> complex protein.
- 2. The method of claim 1, wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F and G.
- 3. The method of claim 1, wherein the neurotoxic component of the <u>botulinum toxin</u> has a molecular weight of about 150 kilodaltons.
- 4. The method of claim 1, wherein the botulinum toxin is a botulinum toxin type A.
- 5. A method for treating strabismus, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a <u>botulinum toxin</u> type A substantially free of a <u>botulinum toxin</u> complex protein.
- 6. A method for treating blepharospasm, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a <u>botulinum toxin</u> substantially free of a <u>botulinum toxin</u> complex protein.
- 7. The method of claim 6, wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F and G.

- 8. The method of claim 6, wherein the neurotoxic component of the botulinum toxin has a molecular weight of about 150 kilodaltons.
 - 9. The method of claim 6, wherein the botulinum toxin is a botulinum toxin type A.
 - 10. A method for treating blepharospasm, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a <u>botulinum toxin</u> type A substantially free of a <u>botulinum toxin</u> complex protein.
 - 11. A method for treating cervical dystonia, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a <u>botulinum toxin</u> substantially free of a <u>botulinum toxin</u> complex protein.
 - 11. The method of claim 11, wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F and G.
- 12. The method of claim 11, wherein the neurotoxic component of the $\underline{\text{botulinum toxin}}$ has a molecular weight of about 150 kilodaltons.
- 13. The method of claim 11, wherein the $\underline{\text{botulinum toxin is a botulinum toxin}}$ type A.
- 14. A method for treating cervical dystonia, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
- 15. A method for treating neuromuscular disorders, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a <u>botulinum toxin</u> substantially free of a <u>botulinum toxin</u> complex protein.
- 16. The method of claim 15, wherein the $\underline{botulinum\ toxin}$ is selected from the group consisting of $\underline{botulinum\ toxin}$ types A, B, C, D, E, F and G.
- 17. The method of claim 15, wherein the neurotoxic component of the $\underline{\text{botulinum toxin}}$ has a molecular weight of about 150 kilodaltons.
- 18. The method of claim 15, wherein the $\underline{\text{botulinum toxin is a botulinum toxin}}$ type A.
- 19. A method for treating a neuromuscular disorder, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
- 20. A method for treating a cholinergic influenced secretion, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin substantially free of a botulinum toxin complex protein.
- 21. The method of claim 20, wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F and G.

- 22. The method of claim 20, wherein the neurotoxic component of the botulinum toxin has a molecular weight of about 150 kilodaltons.
 - 23. The method of claim 20, wherein the $\underline{\text{botulinum toxin}}$ is a $\underline{\text{botulinum toxin}}$ type A.
 - 24. The method of claim 20, wherein the cholinergic influenced secretion is a sweat secretion.
 - 25. A method for treating a cholinergic influenced secretion, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
 - 26. A method for treating a cholinergic influenced sweat secretion, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a botulinum toxin type A substantially free of a botulinum toxin complex protein.
 - 27. A method for treating a neuromuscular disorder or a cholinergic influenced secretion, the method comprising the step of administering to a patient a therapeutically effective amount of a neurotoxic component of a <u>botulinum toxin</u> substantially free of a <u>botulinum toxin</u> complex protein, wherein the neurotoxic component has a molecular weight of about 150 kilodaltons.

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 ${\tt TITLE:}$ Use of ${\tt botulinum\ toxins}$ for treating various disorders and conditions and associated pain

PUBLICATION-DATE: January 17, 2002

INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
Aoki, K. Roger	Laguna Hills	CA	US	
Grayston, Michael W.	Irvine	CA	US	
Carlson, Steven R.	Laguna Niguel	CA	US	
Leon, Judith M.	Laguna Niguel	CA	US	

US-CL-CURRENT: 514/12

CLAIMS:

What is claimed is:

- 1. A method of treating cholinergic controlled secretions including excessive sweating, lacrimation and mucus secretion, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A in order to reduce the secretion.
- 2. The method according to claim 1 wherein the <u>Botulinum toxin</u> type A is administered to the patient's nerve plexus in an amount of between about 0.01 and about 50 units.
- 3. The method according to claim 1 wherein the <u>Botulinum toxin</u> type A is administered to the patient's ganglion in an amount of between about 0.01 and about 50 units.
- 4. The method according to claim 1 wherein the <u>Botulinum toxin</u> type A is administered to the patient's <u>spinal</u> cord in an amount of between about 0.01 and about 50 units.
- 5. The method according to claim 1 wherein the <u>Botulinum toxin</u> type A is administered to the patient's central nervous system in an amount of between about 0.01 and about 50 units.
- 6. A method for relieving pain associated with smooth muscle disorders, including spasms in the sphincters of the cardiovascular arteriole, gastrointestinal system, urinary, gall bladder and rectum, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A in order to relieve pain.

- 7. The method according to claim 6 wherein the <u>Botulinum toxin</u> type A is administered to the patient's pyloric valve in an amount between about 1 and about 50 units.
 - 8. A method for treating smooth muscle disorders, including spasms in the sphincters of the cardiovascular arteriole, gastrointestinal system, urinary, gall bladder and rectum, said method comprising administering to the patient a therapeutically effective amount of <u>Botulinum toxin</u> type A in order to lessen the spasms.
 - 9. The method according to claim 8 wherein the <u>Botulinum toxin</u> type A is administered to the patient's pyloric valve in an amount between about 1 and about 50 units.
 - 10. A method for relieving pain associated with smooth muscle disorders, including spasms in the lower gastrointestinal muscles and rectum, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A in order to relieve pain.
 - 11. The method according to claim 10 wherein the <u>Botulinum toxin</u> type A is administered to the patient's lower colon in an amount between about 0.01 and about 50 units.
- 12. A method for relieving pain associated with smooth muscle disorders, including spasms in the sphincters lower gastrointestinal muscles and rectum, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A in order to lessen the spasms.
- 13. The method according to claim 12 wherein the <u>Botulinum toxin</u> type A is administered to the patient's lower colon in an amount between about 0.01 and about 50 units.
- 14. A method for relieving pain associated with muscle spasms in conditions secondary to sports injuries, said method comprising administering to a patient a therapeutically effective amount of a <u>Botulinum toxin</u> of a type having short duration activity in order to relieve pain.
- 15. The method according to claim 14 wherein the $\underline{\text{Botulinum toxin comprises}}$ $\underline{\text{Botulinum toxin type F.}}$
- 16. The method according to claim 15 wherein the therapeutic amount comprises a dose of between about 1 and about 10 units.
- 17. The method according to claim 16 wherein the muscle spasms occur in a patient's thigh and the <u>Botulinum toxin</u> is administered into the thigh
- 18. A method for relieving pain associated with contractions in arthritis, said method comprising administering to a patient a therapeutically effective amount of a <u>Botulinum toxin</u> in order to relieve pain.
- 19. A method for treating swallowing disorders, including spasms, said method comprising administering to the patient a therapeutically effective amount of Botulinum toxin type A.
- 20. A method for treating tension headache comprising administering to the patient a therapeutically effective amount of <u>Botulinum toxin</u> type A.

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L9: Entry 78 of 122

File: USPT

Oct 1, 2002

DOCUMENT-IDENTIFIER: US 6458365 B1 TITLE: Method for treating headache

Abstract Text (1):

A method and composition for treating a patient suffering from a disease, disorder or condition and associated pain include the administration to the patient of a therapeutically effective amount of a neuronometric selected from a group consisting of of Botulinum toxin types A, B, C, D, E, F and G.

<u>Assignee Name</u> (1): Allergan, Inc.

Detailed Description Text (57):

A male, age 65, with excessive unilateral sweating is treated by administering 0.01 to 50 units, of Botulinum toxin, depending upon degree of desired effect. The larger the dose, usually the greater spread and duration of effect. Small doses are used initially. Any serotype toxin alone or in combination could be used in this indication. The administration is to the gland nerve plexus, ganglion, spinal cord or central nervous system to be determined by the physician's knowledge of the anatomy and physiology of the target glands and secretary cells. In addition, the appropriate spinal cord level or brain area can be injected with the toxin (although (although this would cause many effects, including general weakness). Thus, the gland (if accessible) or the nerve plexus or ganglion are the targets of choice. Excessive sweating, tearing (lacrimation), mucus secretion or gastrointestinal secretions are positively influenced by the cholinergic nervous system. Sweating and tearing are under greater cholinergic control than mucus or gastric secretion and would respond better to toxin treatment. However, mucus and gastric secretions could be modulated through the cholinergic system. All symptoms would be reduced or eliminated with toxin therapy in about 1-7 days. Duration would be weeks to several months.

Detailed Description Text (71):

The Use of Botulinum Toxin Types A-G in the Treatment of Muscle Spasms and Control of Pain Associated with Muscle Spasms in Spasticity Conditions Secondary to Stroke, Traumatic Brain or Spinal Cord Injury

CLAIMS:

- 1. A method for treating tension headache comprising administering to a patient by intramuscular or subcutaneous injection a therapeutically effective amount of Botulinum toxin type A to a muscle of the head or upper neck of the patient, thereby thereby relieving pain of a headache within one to seven days, wherein the headache is associated with a muscle contraction.
- 2. A method for treating headache, the method comprising the step of administering by intramuscular or subcutaneous injection an effective amount of a <u>botulinum toxin</u> to a muscle of the head or upper neck of a patient, thereby relieving a pain of a headache within one to seven days, wherein the headache is associated with a muscle contraction.

- ▼ 3. The method of claim 2, wherein the <u>botulinum toxin</u> is administered in an amount of between 0.01 units and 500 units.
 - 4. The method of claim 2, wherein the <u>botulinum toxin</u> is administered in an amount of between 1 unit and 300 units.
 - 5. The method of claim 2, wherein the botulinum toxin is administered in an amount of between 0.01 units and 50 units.
 - 6. The method of claim 2, wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F and G.
 - 7. The method of claim 2, wherein the $\underline{\text{botulinum toxin}}$ is administered to a human patient.
 - 9. A method for relieving tension headache, the method comprising the step of intramuscular injection into a cholinergic influenced muscle of the head or upper neck of a human patient of a therapeutically effective amount of botulinum toxin in order to relieve a pain associated with a tension headache within one to seven days.
- 11. The method of claim 9, wherein the $\underline{botulinum\ toxin}$ is selected from the group consisting of $\underline{botulinum\ toxin}$ types A, B, C, D, E, F and G.
- 12. A method of treating tension headache comprising administration by intramuscular or subcutaneous injection of a therapeutically effective amount of a botulinum toxin to a patient, thereby relieving pain associated with a tension headache within seven days.
- 13. A method for treating headache, the method comprising the step of administering by intramuscular or subcutaneous injection an effective amount of a <u>botulinum toxin</u> type A to a muscle of the head or upper neck of a patient, thereby relieving a pain of a headache within one to seven days, wherein the headache is associated with a muscle contraction.
- 14. A method for relieving tension headache, the method comprising the step of intramuscular injection into a cholinergic influenced muscle of the head or upper neck of a human patient of a therapeutically effective amount of botulinum toxin type A in order to relieve a pain associated with a tension headache within one to seven days.

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L9: Entry 81 of 122

File: USPT

Jul 23, 2002

DOCUMENT-IDENTIFIER: US 6423319 B1

TITLE: Methods for treating muscle injuries

Abstract Text (1):

Methods for treating an injured muscle by local administration of a neurotoxin, such as a botulinum toxin, to promote healing and/or to reduce the pain associated with an injured muscle.

Assignee Name (1):

Allergan Sales, Inc.

Brief Summary Text (20):

In vitro studies have indicated that botulinum toxin inhibits potassium cation induced release of both acetylcholine and norepinephrine from primary cell cultures of brainstem tissue. Additionally, it has been reported that botulinum toxin inhibits the evoked release of both glycine and glutamate in primary cultures of spinal cord neurons and that in brain synaptosome preparations botulinum toxin inhibits the release of each of the neurotransmitters acetylcholine, dopamine, norepinephrine, CGRP and glutamate.

Brief Summary Text (26):

Typically only a single type of small molecule neurotransmitter is released by each type of neuron in the mammalian nervous system. The neurotransmitter acetylcholine is secreted by neurons in many areas of the brain, but specifically by the large pyramidal cells of the motor cortex, by several different neurons in the basal ganglia, by the motor neurons that innervate the skeletal muscles, by the preganglionic neurons of the autonomic nervous system (both sympathetic and parasympathetic), by the postganglionic neurons of the parasympathetic nervous system, and by some of the postganglionic neurons of the sympathetic nervous system. Essentially, only the postganglionic sympathetic nerve fibers to the sweat glands, the piloerector muscles and a few blood vessels are cholinergic and most of the postganglionic neurons of the sympathetic nervous system release the neurotransmitter norepinephrine. In most instances acetylcholine has an excitatory effect. However, acetylcholine is known to have inhibitory effects at some of the peripheral parasympathetic nerve endings, such as inhibition of the heart by the vagal nerve.

Brief Summary Text (27):

The efferent signals of the autonomic nervous system are transmitted to the body through either the sympathetic nervous system or the parasympathetic nervous system. The preganglionic neurons of the sympathetic nervous system extend from preganglionic sympathetic neuron cell bodies located in the intermediolateral horn of the spinal cord. The preganglionic sympathetic nerve fibers, extending from the cell body, synapse with postganglionic neurons located in either a paravertebral sympathetic ganglion or in a prevertebral ganglion. Since, the preganglionic neurons of both the sympathetic and parasympathetic nervous system are cholinergic, application of acetylcholine to the ganglia will excite both sympathetic and parasympathetic postganglionic neurons.

CLAIMS:

- 1. A method for treating an injured muscle, the method comprising the step of local administration of a therapeutically effective amount of a <u>botulinum toxin</u> to an injured muscle, thereby treating the injured muscle by promoting healing of the injured muscle within six weeks after the local administration of the <u>botulinum</u> toxin.
- 2. The method of claim 1, wherein the botulinum toxin is intramuscularly injected.
- 3. The method of claim 1, wherein the $\underline{botulinum\ toxin}$ immobilizes the injured muscle.
- 4. The method of claim 1, wherein the $\underline{botulinum\ toxin}$ is effective to immobilize the the injured muscle during phase 1 and phase 2 of a repair process of the injured muscle.
- 5. The method of claim 1, wherein the <u>botulinum toxin</u> is effective to immobilize the the injured muscle during phase 1 of a repair process of the injured muscle.
- 6. The method of claim 1, wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum toxin</u> type A, B, C.sub.1, D, E, F, and G.
- 7. The method of claim 1, wherein the $\underline{botulinum\ toxin}$ is a recombinantly made $\underline{botulinum\ toxin}$.
- 9. The method of claim 1, wherein the botulinum toxin is botulinum toxin type A.
- 10. The method of claim 1, wherein the botulinum toxin is botulinum toxin type B.
- 11. A method for treating an injured muscle, the method comprising the step of local administration of a therapeutically effective amount of a botulinum toxin type A to an injured muscle, thereby treating the injured muscle by promoting healing of the injured muscle within six weeks after the local administration of the botulinum toxin type A.

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Merriam-Webster Inc. Company information

Merriam-Webster Online Dictionary

Thesaurus

Main Entry: in-tra-the-cal •) Pronunciation: - 'thE-k&1

One entry found for intrathecal.

Function: adjective

: introduced into or occurring in the space under the arachnoid membrane of the brain or spinal cord

- in tra the cally □) /-k(&-) 1E/ adverb

For More Information on "intrathecal" go to Britannica.com Get the Top 10 Search Results for "intrathecal"

Pronunciation Symbols

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Intrathecal

<anatomy> Within a sheath, for example, cerebrospinal fluid that is contained within the dura mater. It also refers to drugs administered into the cerebrospinal fluid bathing the spinal cord and brain.

(30 Sep 1997)

Previous: <u>intrastromal</u>, <u>intrasynovial</u>, <u>intratarsal</u>, <u>intratendinous bursa of elbow</u> **Next**: <u>intrathecal chemotherapy</u>, <u>intrathecal injection</u>, <u>intrathoracic</u>

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L5: Entry 7 of 14

File: USPT

Sep 23, 2003

US-PAT-NO: 6623742

DOCUMENT-IDENTIFIER: US 6623742 B2

TITLE: Methods for treating fibromyalgia

DATE-ISSUED: September 23, 2003

INVENTOR-INFORMATION:

NAME

CITY

STATE ZIP CODE

COUNTRY

Voet; Martin A.

San Juan Capistrano

 $C\Delta$

 $\text{US-CL-CURRENT: } \underline{424/236.1}; \ \underline{424}/\underline{247.1}, \ \underline{435/71.3}, \ \underline{514}/\underline{12}, \ \underline{514/2}, \ \underline{530/344}, \ \underline{530/350}$

CLAIMS:

What is claimed is:

- 1. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient afflicted with fibromyalgia, wherein the peripheral location is not a locus of pain, and wherein the locus of pain and the site of administration are located within a same dermatome, thereby relieving a fibromyalgia pain for at least one month.
- 2. The method of claim 1 wherein the <u>peripheral</u> location is in a head of the patient, and wherein the locus of pain is not in the head of the patient.
- 3. The method of claim 1 wherein the <u>peripheral</u> location is in a head of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
- 4. The method of claim 1 wherein the <u>peripheral</u> location is in a cranial area or a facial area of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
- 5. The method of claim 1 wherein the <u>botulinum toxin</u> is selected from the group group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F, and G.
- 6. The method of claim 1 wherein the $\underline{botulinum\ toxin}\ is\ a\ botulinum\ toxin}$ type A.
- 7. The method of claim 1 wherein the location of <u>peripheral</u> administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 8. The method of claim 1 wherein the $\underline{\text{botulinum toxin}}$ is administered with a needle.
- 9. The method of claim 1 wherein the botulinum toxin is administered by

needleless injection.

- 10. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, and wherein the peripheral location is not at the locus of pain, and the locus of pain and the site of administration are located within a same dermatome, thereby relieving the pain for at least one month.
- 11. The method of claim 10 wherein the patient has at least eleven loci of pain.
- 12. The method of claim 10 wherein the <u>botulinum toxin</u> is selected from the group consisting of botulinum neurotoxin types A, B, C, D, E, F, and G.
- 13. The method of claim 10 wherein the <u>botulinum toxin</u> is a <u>botulinum toxin</u> type A.
- 14. The method of claim 10 wherein the location of <u>peripheral</u> administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 15. The method of claim 10 wherein the $\underline{\text{botulinum toxin}}$ is administered with a needle.
- 16. The method of claim 10 wherein the $\underline{botulinum\ toxin}$ is administered by needleless injection.
- 17. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a <u>botulinum toxin</u> to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain, wherein the administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.
- 18. The method of claim 17 wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum toxin types A, B, C, D, E, F, and G.</u>
- 19. The method of claim 17 wherein the $\underline{\text{botulinum toxin is a botulinum toxin}}$ type A.
- 20. The method of claim 17 wherein the location of administration and the locus locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 21. The method of claim 17 wherein the $\underline{\text{botulinum toxin}}$ is administered with a needle.
- 22. The method of claim 17 wherein the $\underline{\text{botulinum toxin}}$ is administered by needleless injection.
- 23. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a <u>botulinum toxin</u> to a dermatome of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, wherein the dermatome

encompasses 50% or more of the locus of pain, and wherein the administration is is not at the locus of pain, thereby relieving the pain for at least one month. month.

- 24. The method of claim 23 wherein the patient has at least eleven loci of pain.
- 25. The method of claim 23 wherein the locus of pain and the <u>peripheral</u> location are located within a dermatome.
- 26. The method of claim 23 wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F, and G.
- 27. The method of claim 23 wherein the $\underline{\text{botulinum toxin}}$ is a $\underline{\text{botulinum toxin}}$ type A.
- 28. The method of claim 23 wherein the location of administration and the locus locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 29. The method of claim 23 wherein the $\underline{\text{botulinum toxin}}$ is administered with a needle.
- 30. The method of claim 23 wherein the $\underline{\text{botulinum toxin}}$ is administered by needleless injection.
- 31. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain which is at a fibromyalgia tender point, and wherein the local administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.
- 32. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a <u>botulinum toxin</u> type A to a dermatome of a patient, wherein the patient has a locus of pain which is at a fibromyalgia tender point, wherein the dermatome encompasses 50% or more of the locus of pain, and wherein the administration is not at the locus of pain, thereby relieving the pain for at least one month.

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L9: Entry 70 of 122

File: USPT

Sep 23, 2003

US-PAT-NO: 6623742

DOCUMENT-IDENTIFIER: US 6623742 B2

TITLE: Methods for treating fibromyalgia

DATE-ISSUED: September 23, 2003

INVENTOR-INFORMATION:

NAME

CITY

STATE ZIP CODE COUNTRY

Voet; Martin A. San Juan Capistrano

CA

US-CL-CURRENT: 424/236.1; 424/247.1, 435/71.3, 514/12, 514/2, 530/344, 530/350

CLAIMS:

J.

What is claimed is:

- 1. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin to a peripheral location of a body of a patient afflicted with fibromyalgia, wherein the peripheral location is not a locus of pain, and wherein the locus of pain and the site of administration are located within a same dermatome, thereby relieving a fibromyalgia pain for at least one month.
- 2. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is not in the head of the patient.
- 3. The method of claim 1 wherein the peripheral location is in a head of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
- 4. The method of claim 1 wherein the peripheral location is in a cranial area or a facial area of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
- 5. The method of claim 1 wherein the botulinum toxin is selected from the group group consisting of botulinum toxin types A, B, C, D, E, F, and G.
- 6. The method of claim 1 wherein the botulinum toxin is a botulinum toxin type A.
- 7. The method of claim 1 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 8. The method of claim 1 wherein the botulinum toxin is administered with a needle.
- 9. The method of claim 1 wherein the botulinum toxin is administered by

needleless injection.

- 10. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a <u>botulinum toxin</u> to a peripheral location of a body of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, and wherein the peripheral location is not at the locus of pain, and the locus of pain and the site of administration are located within a same dermatome, thereby relieving the pain for at least one month.
- 11. The method of claim 10 wherein the patient has at least eleven loci of pain.
- 12. The method of claim 10 wherein the <u>botulinum toxin</u> is selected from the group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F, and G.
- 13. The method of claim 10 wherein the $\underline{\text{botulinum toxin is a botulinum toxin}}$ type A.
- 14. The method of claim 10 wherein the location of peripheral administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 15. The method of claim 10 wherein the $\underline{\text{botulinum toxin}}$ is administered with a needle.
- 16. The method of claim 10 wherein the $\underline{\text{botulinum toxin}}$ is administered by needleless injection.
- 17. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a <u>botulinum toxin</u> to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain, wherein the administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.
- 18. The method of claim 17 wherein the $\underline{botulinum\ toxin}$ is selected from the group consisting of $\underline{botulinum\ toxin}$ types A, B, C, D, E, F, and G.
- 19. The method of claim 17 wherein the $\underline{\text{botulinum toxin}}$ is a $\underline{\text{botulinum toxin}}$ type A.
- 20. The method of claim 17 wherein the location of administration and the locus locus of pain have neuronal processes that are projected from the same $\underline{\text{spinal}}$ sensory nerve root.
- 21. The method of claim 17 wherein the <u>botulinum toxin</u> is administered with a needle.
- 22. The method of claim 17 wherein the $\underline{\text{botulinum toxin}}$ is administered by needleless injection.
- 23. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a <u>botulinum toxin</u> to a dermatome of a patient, wherein the patient has a locus of pain at a fibromyalgia tender point, wherein the dermatome

encompasses 50% or more of the locus of pain, and wherein the administration is is not at the locus of pain, thereby relieving the pain for at least one month. month.

- 24. The method of claim 23 wherein the patient has at least eleven loci of pain.
- 25. The method of claim 23 wherein the locus of pain and the peripheral location are located within a dermatome.
- 26. The method of claim 23 wherein the $\underline{botulinum\ toxin}$ is selected from the group consisting of $\underline{botulinum\ neurotoxin}$ types A, B, C, D, E, F, and G.
- 27. The method of claim 23 wherein the $\underline{\text{botulinum toxin}}$ is a $\underline{\text{botulinum toxin}}$ type A.
- 28. The method of claim 23 wherein the location of administration and the locus locus of pain have neuronal processes that are projected from the same <u>spinal</u> sensory nerve root.
- 29. The method of claim 23 wherein the $\underline{\text{botulinum toxin}}$ is administered with a needle.
- 30. The method of claim 23 wherein the $\underline{botulinum\ toxin}$ is administered by needleless injection.
- 31. A method for treating fibromyalgia, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome encompasses 50% or more of a locus of pain which is at a fibromyalgia tender point, and wherein the local administration is not at the locus of pain, thereby relieving a fibromyalgia pain for at least one month.
- 32. A method for treating fibromyalgia pain, the method comprising the step of administering subcutaneously or intramuscularly a therapeutically effective amount of a <u>botulinum toxin</u> type A to a dermatome of a patient, wherein the patient has a locus of pain which is at a fibromyalgia tender point, wherein the dermatome encompasses 50% or more of the locus of pain, and wherein the administration is not at the locus of pain, thereby relieving the pain for at least one month.

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L5: Entry 1 of 14

File: PGPB

Apr 1, 2004

PGPUB-DOCUMENT-NUMBER: 20040062776

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040062776 A1

TITLE: Botulinum toxin therapy for fibromyalgia

PUBLICATION-DATE: April 1, 2004

INVENTOR-INFORMATION:

NAME

CITY

STATE

RULE-47

Voet, Martin A.

San Juan Capistrano

CA

US

COUNTRY

US-CL-CURRENT: 424/239.1

CLAIMS:

I claim:

- 1. A method for treating fibromyalgia, the method comprising the step of administering a botulinum toxin to a patient afflicted with fibromyalgia.
- 2. The method of claim 1 wherein the <u>botulinum toxin</u> is selected form the group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F and G.
- 3. The method of claim 1 wherein the <u>botulinum toxin is a botulinum neurotoxin</u> type A.
- 4. The method of claim 1 wherein the <u>botulinum toxin</u> is administered subcutaneously.
- 5. The method of claim 1 wherein the <u>botulinum toxin</u> is administered intramuscularly.
- 6. A method for treating a fibromyalgia pain, the method comprising the step of administering locally a therapeutically effective amount of a <u>botulinum neurotoxin</u> to a patient with a fibromyalgia pain, thereby treating the fibromyalgia pain.
- 7. The method of claim 6 wherein the <u>botulinum neurotoxin</u> is selected from the group group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F and G.
- 8. The method of claim 6 wherein the $\underline{\text{botulinum neurotoxin}}$ is a $\underline{\text{botulinum neurotoxin}}$ type A.
- 9. The method of claim 6 wherein the <u>botulinum neurotoxin</u> is administered subcutaneously or intramuscularly.

- 10. A method for treating fibromyalgia, the method comprising the step of administering a botulinum toxin to a patient with fibromyalgia, the botulinum toxin administering being carried out at a first location which first location is anatomically distinct from and/or anatomically distant from a second location, at which second location the patient has a fibromyalgia pain which is alleviated by the administration of the botulinum toxin at the first location, thereby treating fibromyalgia.
- 11. The method of claim 10, wherein the first location is a peripheral location.
- 12. The method of claim 10, wherein the second location is a locus of pain.
- 13. The method of claim 10, wherein the administering step is carried out by subcutaneous or intramuscular administering of the botulinum toxin.
- 14. The method of claim 10, wherein the first location is the head or neck of the patient.

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L5: Entry 2 of 14

File: PGPB

Jan 29, 2004

PGPUB-DOCUMENT-NUMBER: 20040018213

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040018213 A1

TITLE: Pain treatment by peripheral administration of a neurotoxin

PUBLICATION-DATE: January 29, 2004

INVENTOR-INFORMATION:

NAME CITY STATE COUNTRY RULE-47 Aoki, Kei Roger Coto de Caza CA US Cui, Minglei Irvine US Jenkins, Stephen W. Mission Viejo CA US

US-CL-CURRENT: 424/239.1

CLAIMS:

We claim:

- 1. A method for treating pain, the method comprising the step of <u>peripheral</u> administration of a <u>neurotoxin</u> to a mammal, wherein the pain treated is not associated with a muscle spasm.
- 2. The method of claim 1, wherein the $\underline{neurotoxin}$ comprises a neuronal binding moiety moiety which is substantially native to the $\underline{neurotoxin}$.
- 3. The method of claim 1, wherein the neurotoxin is a botulinum toxin.
- 4. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is a botulinum toxin elected from the group consisting of $\underline{\text{botulinum toxin}}$ types A, B, C.sub.1, D, E, F and G.
- 5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
- 6. The method of claim 1, wherein the $\underline{neurotoxin}$ is a modified $\underline{neurotoxin}$ having at least one amino acid deleted, modified or replaced.
- 7. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is made at least in part by recombinant process.
- 8. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is administered in an amount between about 0.01 U/kg and about 35 U/kg.
- 9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.

- 10. The method of claim 1, wherein the <u>peripheral</u> administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.
- 11. The method of claim 1, wherein the <u>peripheral</u> administration is carried out subsequent to an onset of a nociceptive event experienced by the mammal.
- 12. A method for alleviating pain, the method comprising the step of <u>peripheral</u> administration of a <u>botulinum toxin</u> to a human patient, thereby alleviating pain, wherein the pain is not associated with a muscle disorder.
- 13. The method of claim 12, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
- 14. A method for treating a pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the neurotoxin is a polypeptide comprising: a) a first amino acid sequence region comprising a wild type neuronal binding moiety, substantially completely derived from a neurotoxin selected from a group consisting botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof; b) a second amino acid sequence region effective to translocate the polypeptide or a part thereof across an endosome membrane; and c) a third amino acid sequence region having therapeutic activity when released into a cytoplasm of a target cell, wherein the pain is not associated with a muscle spasm.
- 15. The method of claim 14, wherein the first amino acid sequence region of the polypeptide comprises a carboxyl terminal of a heavy chain derived from the $\underline{\text{neurotoxin}}$.
- 16. The method of claim 14, wherein the neurotoxin is botulinum toxin type A.
- 17. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a heavy chain derived from a neurotoxin selected from a group consisting of botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 18. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a <u>toxin</u> heavy chain derived from <u>botulinum toxin</u> type A.
- 19. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from a neurotoxin selected from a group consisting of beratti toxin; butyricum toxin; tetani toxin; botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 20. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from botulinum toxin type A.
- 21. A method for improving patient function, the method comprising the step of peripheral administration of a botulinum toxin to a patient experiencing a non-muscle disorder related pain, thereby improving patient function as determined by improvement in one or more of the factors of reduced pain, reduced time spent in bed, improve hearing, increased ambulation, healthier attitude and a more varied lifestyle.
- 22. A method for treating post-operative pain, the method comprising the step of <u>peripheral</u> administration of an effective amount of a <u>botulinum toxin</u> before, during during or immediately after a surgical procedure, thereby alleviating a post-operative pain, wherein the surgical procedure is not carried out to treat a muscle

spasm.

- 23 A method for treating a visceral pain the method comprising the step of non-systemic, local administration of an effective amount of a <u>botulinum toxin</u>, thereby alleviating a visceral pain.
- 24. A method for treating pain, the method comprising the step of <u>peripheral</u> administration of a <u>neurotoxin</u> to a mammal, wherein the pain is not substantially due to a muscle spasm.
- 25. The method of claim 24, wherein, the neurotoxin is a botulinum toxin.
- 26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.
- 27. The method of claim 24, wherein the <u>peripheral</u> administration is by subcutaneous administration of the neurotoxin.

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L5: Entry 3 of 14

File: PGPB

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Jan 29, 2004

PGPUB-DOCUMENT-NUMBER: 20040018212

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040018212 A1

TITLE: Joint pain treatment by peripheral administration of a neurotoxin

PUBLICATION-DATE: January 29, 2004

INVENTOR-INFORMATION:

NAME CITY STATE COUNTRY RULE-47 Aoki, Kei Roger Coto de Caza CA US Cui, Minglei Irvine CA US Jenkins, Stephen W. Mission Viejo CA US

US-CL-CURRENT: 424/239.1

CLAIMS:

We claim:

- 1. A method for treating pain, the method comprising the step of <u>peripheral</u> administration of a <u>neurotoxin</u> to a mammal, wherein the pain treated is not associated with a muscle spasm.
- 2. The method of claim 1, wherein the $\underline{neurotoxin}$ comprises a neuronal binding moiety moiety which is substantially native to the $\underline{neurotoxin}$.
- 3. The method of claim 1, wherein the neurotoxin is a botulinum toxin..
- 4. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is a botulinum $\underline{\text{toxin}}$ elected from the group consisting of $\underline{\text{botulinum}}$ toxin types A, B, C.sub.1, D, E, F and G.
- 5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
- 6. The method of claim 1, wherein the $\underline{neurotoxin}$ is a modified $\underline{neurotoxin}$ having at least one amino acid deleted, modified or replaced.
- 7. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is made at least in part by a recombinant process.
- 8. The method of claim 1, wherein the $\underline{neurotoxin}$ is administered in an amount between about 0.01 U/kg and about 35 U/kg.
- 9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.

- 10. The method of claim 1, wherein the <u>peripheral</u> administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.
- 11. The method of claim 1, wherein the <u>peripheral</u> administration is carried out subsequent to an onset of a nociceptive event experienced by the mammal.
- 12. A method for alleviating pain, the method comprising the step of <u>peripheral</u> administration of a <u>botulinum toxin</u> to a human patient, thereby alleviating pain, wherein the pain is not associated with a muscle disorder.
- 13. The method of claim 12, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
- 14. A method for treating a pain, the method comprising the step of periph ral administration of a neurotoxin to a mammal, wherein the neurotoxin is a polypeptide comprising: a) a first amino acid sequence region comprising a wild type neuronal binding moiety, substantially completely derived from a neurotoxin selected from a group consisting botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof; b) a second amino acid sequence region effective to translocate the polypeptide or a part thereof across an endosome membrane; and c) a third amino acid sequence region having therapeutic activity when released into a cytoplasm of a target cell, wherein the pain is not associated with a muscle spasm.
- 15. The method of claim 14, wherein the first amino acid sequence region of the polypeptide comprises a carboxyl terminal of a heavy chain derived from the neurotoxin.
- 16. The method of claim 14, wherein the neurotoxin is botulinum toxin type A.
- 17. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a heavy chain derived from a neurotoxin selected from a group consisting of botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 18. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a <u>toxin</u> heavy chain derived from <u>botulinum toxin</u> type A.
- 19. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a <u>toxin</u> light chain derived from a <u>neurotoxin</u> selected from a group consisting of beratti <u>toxin</u>; butyricum <u>toxin</u>; tetani <u>toxin</u>; botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 20. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a <u>toxin</u> light chain derived from <u>botulinum toxin</u> type A.
- 21. A method for improving patient function, the method comprising the step of peripheral administration of a botulinum toxin to a patient experiencing a non-muscle disorder related pain, thereby improving patient function as determined by improv ment in one or more of the factors of reduced pain, reduced time spent in bed, improve hearing, increased ambulation, healthier attitude and a more varied lifestyle.
- 22. A method for treating post-operative pain, the method comprising the st p of peripheral administration of an effective amount of a botulinum toxin before, during during or immediately after a surgical procedure, thereby alleviating a post-operative pain, wherein the surgical procedure is not carried out to treat a muscle

spasm.

- 23. A method for treating a visceral pain the method comprising the step of non-systemic, local administration of an effective amount of a <u>botulinum toxin</u>, thereby alleviating a visceral pain.
- 24. A method for treating pain, the method comprising the step of <u>peripheral</u> administration of a <u>neurotoxin</u> to a mammal, wherein the pain is not substantially due to a muscle spasm.
- 25. The method of claim 24, wherein, the neurotoxin is a botulinum toxin.
- 26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.
- 27. The method of claim 24, wherein the $\underline{peripheral}$ administration is by subcutaneous administration of the neurotoxin.

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WEST Search History

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DATE: Tuesday, July 06, 2004

Hide?	<u>Set</u> Name	Query	<u>Hit</u> <u>Count</u>
	DB=PC	GPB,USPT,USOC,EPAB,JPAB,DWPI,TDBD; PLUR=YES; OP=AND	
1 10	L1	schizophren\$	15305
	L2	L1 and (donovan.in. or allergan.asn.)	3
	L3	(donovan.in. or allergan.asn.)	5142
	L4	L3 and peripheral.ti,ab,clm.	135
	L5	L4 and (botulinum or botulism or botox or neurotoxin or neuro-toxin or toxin or clostrid\$)	14

END OF SEARCH HISTORY

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Search Results - Record(s) 1 through 14 of 14 returned.

☐ 1. <u>20040062776</u> . 18 Sep 03. 01 Apr 04. <u>Botulinum toxin</u> therapy for fibromyalgia. Voet, Martin A 424/239.1; A61K039/08.
2. 20040018213. 29 Jul 03. 29 Jan 04. Pain treatment by peripheral administration of a neurotoxin. Aoki, Kei Roger, et al. 424/239.1; A61K039/08.
3. 20040018212. 29 Jul 03. 29 Jan 04. Joint pain treatment by peripheral administration of a neurotoxin. Aoki, Kei Roger, et al. 424/239.1; A61K039/08.
4. <u>20030054975</u> . 17 Sep 01. 20 Mar 03. Methods for treating fibromyalgia. Voet, Martin A 514/2; A61K038/16.
5. 20020176872. 18 Jul 02. 28 Nov 02. Pain treatment by peripheral administration of a neurotoxin. Aoki, Kei Roger, et al. 424/247.1; A61K039/08.
☐ 6. <u>20020028216</u> . 04 Oct 01. 07 Mar 02. <u>Botulinum toxin</u> implant. <u>Donovan</u> , Stephen. 424/236.1; A61K039/02.
☐ 7. <u>6623742</u> . 17 Sep 01; 23 Sep 03. Methods for treating fibromyalgia. Voet; Martin A 424/236.1; 424/247.1 435/71.3 514/12 514/2 530/344 530/350. A61K039/08 C07K014/33.
8. <u>6506399</u> . 04 Oct 01; 14 Jan 03. Biodegradable <u>botulinum toxin</u> implant. <u>Donovan</u> ; Stephen. 424/423; 424/184.1 424/236.1 424/422 424/426. A61K039/02 A61K039/00.
9. <u>6312708</u> . 21 Jul 00; 06 Nov 01. <u>Botulinum toxin</u> implant. <u>Donovan</u> ; Stephen. 424/423; 424/184.1 424/236.1 424/422 424/426. A61K039/02 A61K039/00.
10. WO2003099289A. Alleviation of pain e.g. neuropathic pain, visceral pain, post-operative pain, inflammatory pain, arthritic pain involves use of a composition comprising alpha-adrenergic agonist and a composition comprising selective alpha-2A antagonist. DONELLO, J E, et al. A61K031/137 A61K031/4164 A61K031/4166 A61K031/4168 A61K031/4178 A61K031/498 A61K031/538 A61P029/00.
11. <u>US20030054975A</u> . Treatment of pain associated with fibromyalgia involves locally administering <u>Clostridial neurotoxin to peripheral</u> location of patient's body afflicted with fibromyalgia, where the location is not locus of pain. VOET, M A. A61K038/16 A61K039/08 C07K014/33.
12. <u>US20030027752A</u> . Novel modified <u>neurotoxin</u> with a structural modification that alters biological persistence or activity of the modified <u>neurotoxin</u> relative to the unmodified <u>neurotoxin</u> , for treating tremors, bruxism and dysphagia. AOKI, K R, et al. A61K038/17 C07K014/435.
13. WO 200208268A. Novel modified neurotoxin comprising structural modification which alters the biological persistence and/or biological activity of a neurotoxin, useful for treating neuromuscular or autonomic disorder, or pain. AOKI, K R, et al. A61K038/16 A61P021/00 A61P029/02 A61P037/00 C07K014/33.

14. <u>US 6464986B</u>. Treating a non-spasm caused pain involves <u>peripheral</u> administration of a <u>neurotoxin</u> to mammal. AOKI, K R, et al. A61K038/00 A61K038/16 A61K038/48 A61K039/02 A61K039/08 A61K045/00 A61P025/02 A61P029/02.

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Terms	Documents
L4 and (botulinum or botulism or botox or neurotoxin or neuro-toxin	14
or toxin or clostrid\$)	

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L5: Entry 1 of 14

File: PGPB

Apr 1, 2004

PGPUB-DOCUMENT-NUMBER: 20040062776

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040062776 A1

TITLE: Botulinum toxin therapy for fibromyalgia

PUBLICATION-DATE: April 1, 2004

INVENTOR - INFORMATION:

NAME

CITY

STATE

COUNTRY RULE-47

Voet, Martin A.

San Juan Capistrano

CA

ASSIGNEE-INFORMATION:

NAME

CITY

STATE COUNTRY

TYPE CODE

02

US

Allergan, Inc.

APPL-NO: 10/ 666408 [PALM]
DATE FILED: September 18, 2003

RELATED-US-APPL-DATA:

Application 10/666408 is a continuation-in-part-of US application 09/954610, filed September 17, 2001, US Patent No. 6623742

INT-CL: [07] A61 K 39/08

US-CL-PUBLISHED: 424/239.1 US-CL-CURRENT: 424/239.1

REPRESENTATIVE-FIGURES: NONE

ABSTRACT:

Methods for treating fibromyalgia by administering a therapeutically effective amount of a botulinum toxin to a patient with fibromyalgia.

CROSS REFERENCE

[0001] This application is a continuation in part of U.S. patent application Ser. No. 09/954,610, filed Sep. 17, 2001.

L5: Entry 1 of 14

File: PGPB

Apr 1, 2004

PGPUB-DOCUMENT-NUMBER: 20040062776

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040062776 A1

TITLE: Botulinum toxin therapy for fibromyalgia

PUBLICATION-DATE: April 1, 2004

INVENTOR-INFORMATION:

NAME

CITY

STATE

COUNTRY RULE-47

Voet, Martin A.

San Juan Capistrano

CA

US-CL-CURRENT: 424/239.1

CLAIMS:

I claim:

- 1. A method for treating fibromyalgia, the method comprising the step of administering a botulinum toxin to a patient afflicted with fibromyalgia.
- 2. The method of claim 1 wherein the <u>botulinum toxin</u> is selected form the group consisting of <u>botulinum toxin</u> types A, B, C, D, E, F and G.
- 3. The method of claim 1 wherein the $\underline{\text{botulinum toxin is a botulinum neurotoxin}}$ type A.
- 4. The method of claim 1 wherein the $\underline{\text{botulinum toxin}}$ is administered subcutaneously. subcutaneously.
- 5. The method of claim 1 wherein the <u>botulinum toxin</u> is administered intramuscularly.
- 6. A method for treating a fibromyalgia pain, the method comprising the step of administering locally a therapeutically effective amount of a <u>botulinum neurotoxin</u> to a patient with a fibromyalgia pain, thereby treating the fibromyalgia pain.
- 7. The method of claim 6 wherein the <u>botulinum neurotoxin</u> is selected from the group group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F and G.
- 8. The method of claim 6 wherein the $\underline{\text{botulinum neurotoxin}}$ is a $\underline{\text{botulinum neurotoxin}}$ type A.
- 9. The method of claim 6 wherein the $\underline{\text{botulinum neurotoxin}}$ is administered subcutaneously or intramuscularly.
- 10. A method for treating fibromyalgia, the method comprising the step of administering a botulinum toxin to a patient with fibromyalgia, the botulinum toxin

administering being carried out at a first location which first location is anatomically distinct from and/or anatomically distant from a second location, at which second location the patient has a fibromyalgia pain which is alleviated by the the administration of the botulinum toxin at the first location, thereby treating fibromyalgia.

- 11. The method of claim 10, wherein the first location is a peripheral location.
- 12. The method of claim 10, wherein the second location is a locus of pain.
- 13. The method of claim 10, wherein the administering step is carried out by subcutaneous or intramuscular administering of the botulinum toxin.

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☐ 1. Document ID: US 20030211121 A1

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L2: Entry 1 of 3

File: PGPB

Nov 13, 2003

PGPUB-DOCUMENT-NUMBER: 20030211121

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20030211121 A1

TITLE: Therapeutic treatments for neuropsychiatric disorders

PUBLICATION-DATE: November 13, 2003

INVENTOR-INFORMATION:

NAME

CITY

STATE

RULE-47

Donovan, Stephen

Capistrano Beach

CA

US

COUNTRY

US-CL-CURRENT: 424/247.1

Full | Title | Citation | Front | Review | Classification | Date | Reference | Sequences | Attachments | Claims | KWIC | Draw, D.

☐ 2. Document ID: US 6306403 B1

L2: Entry 2 of 3

File: USPT

Oct 23, 2001

DOCUMENT-IDENTIFIER: US 6306403 B1

TITLE: Method for treating parkinson's disease with a botulinum toxin

INVENTOR (1):

Donovan; Stephen

Assignee Name (1):

Allergan Sales, Inc.

Other Reference Publication (21):

Hoffman, Ralph E., et al., Transcranial magnetic stimulation and auditory hallucinations in schizophrenia; The Lancet vol. 355, Mar. 25, 2000, 1073-1075.

Full Title Citation Front Review Classification Date Reference Sequences Attachnesis Claims KMC Draw. De

3. Document ID: WO 2003094955 A1, US 20030211121 A1

L2: Entry 3 of 3

File: DWPI

Nov 20, 2003

DERWENT-ACC-NO: 2003-901566

DERWENT-WEEK: 200403

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TITLE: Treating a neuropsychiatric disorder, e.g. schizophrenia, Alzheimer's disease, mania or anxiety, comprises administering intracranially a clostridial neurotoxin or a botulinum toxin to a patient

INVENTOR: DONOVAN, S

PRIORITY-DATA: 2002US-0143078 (May 10, 2002)

PATENT-FAMILY:

PUB-NO

PUB-DATE

LANGUAGE

Е

PAGES MAIN-IPC

WO 2003094955 A1

November 20, 2003

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A61K038/48

US 20030211121 A1

November 13, 2003

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A61K039/08

INT-CL (IPC): A61 K 38/48; A61 K 39/08; A61 P 25/18; A61 P 25/22; A61 P 25/28

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L5: Entry 2 of 14

File: PGPB

Jan 29, 2004

PGPUB-DOCUMENT-NUMBER: 20040018213

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040018213 A1

TITLE: Pain treatment by peripheral administration of a neurotoxin

PUBLICATION-DATE: January 29, 2004

INVENTOR-INFORMATION:

NAME	CITY	STATE	COUNTRY	RULE-47
Aoki, Kei Roger	Coto de Caza	CA	us	
Cui, Minglei	Irvine	CA	US	
Jenkins, Stephen W.	Mission Viejo	CA	US	

US-CL-CURRENT: 424/239.1

CLAIMS:

We claim:

- 1. A method for treating pain, the method comprising the step of <u>peripheral</u> administration of a <u>neurotoxin</u> to a mammal, wherein the pain treated is not associated with a muscle spasm.
- 2. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ comprises a neuronal binding moiety moiety which is substantially native to the $\underline{\text{neurotoxin}}$.
- 3. The method of claim 1, wherein the neurotoxin is a botulinum toxin.
- 4. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is a botulinum $\underline{\text{toxin}}$ elected from the group consisting of $\underline{\text{botulinum}}$ toxin types A, B, C.sub.1, D, E, F and G.
- 5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
- 6. The method of claim 1, wherein the $\underline{neurotoxin}$ is a modified $\underline{neurotoxin}$ having at least one amino acid deleted, modified or replaced.
- 7. The method of claim 1, wherein the $\underline{neurotoxin}$ is made at least in part by recombinant process.
- 8. The method of claim 1, wherein the $\underline{neurotoxin}$ is administered in an amount between about 0.01 U/kg and about 35 U/kg.
- 9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.
- 10. The method of claim 1, wherein the <u>peripheral</u> administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.

- 11. The method of claim 1, wherein the <u>peripheral</u> administration is carried out subsequent to an onset of a nociceptive event experienced by the mammal.
- 12. A method for alleviating pain, the method comprising the step of <u>peripheral</u> administration of a <u>botulinum toxin</u> to a human patient, thereby alleviating pain, wherein the pain is not associated with a muscle disorder.
- 13. The method of claim 12, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
- 14. A method for treating a pain, the method comprising the step of peripheral administration of a neurotoxin to a mammal, wherein the neurotoxin is a polypeptide comprising: a) a first amino acid sequence region comprising a wild type neuronal binding moiety, substantially completely derived from a neurotoxin selected from a group consisting botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof; b) a second amino acid sequence region effective to translocate the polypeptide or a part thereof across an endosome membrane; and c) a third amino acid sequence region having therapeutic activity when released into a cytoplasm of a target cell, wherein the pain is not associated with a muscle spasm.
- 15. The method of claim 14, wherein the first amino acid sequence region of the polypeptide comprises a carboxyl terminal of a heavy chain derived from the $\underline{\text{neurotoxin}}$.
- 16. The method of claim 14, wherein the neurotoxin is botulinum toxin type A.
- 17. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a heavy chain derived from a <u>neurotoxin</u> selected from a group consisting of <u>botulinum toxin</u> types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 18. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a toxin heavy chain derived from botulinum toxin type A.
- 19. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a <u>toxin</u> light chain derived from a <u>neurotoxin</u> selected from a group consisting of beratti <u>toxin</u>; butyricum <u>toxin</u>; tetani <u>toxin</u>; botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 20. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from botulinum toxin type A.
- 21. A method for improving patient function, the method comprising the step of peripheral administration of a botulinum toxin to a patient experiencing a non-muscle disorder related pain, thereby improving patient function as determined by improvement in one or more of the factors of reduced pain, reduced time spent in bed, improve hearing, increased ambulation, healthier attitude and a more varied lifestyle.
- 22. A method for treating post-operative pain, the method comprising the step of peripheral administration of an effective amount of a <a href="mailto:bot
- 23 A method for treating a visceral pain the method comprising the step of non-

systemic, local administration of an effective amount of a $\underline{\text{botulinum toxin}}$, thereby alleviating a visceral pain.

- 24. A method for treating pain, the method comprising the step of <u>peripheral</u> administration of a <u>neurotoxin</u> to a mammal, wherein the pain is not substantially due to a muscle spasm.
- 25. The method of claim 24, wherein, the neurotoxin is a botulinum toxin.
- 26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.
- 27. The method of claim 24, wherein the $\underline{peripheral}$ administration is by subcutaneous administration of the $\underline{neurotoxin}$.

L5: Entry 3 of 14

File: PGPB

Jan 29, 2004

PGPUB-DOCUMENT-NUMBER: 20040018212

PGPUB-FILING-TYPE: new

DOCUMENT-IDENTIFIER: US 20040018212 A1

TITLE: Joint pain treatment by peripheral administration of a neurotoxin

PUBLICATION-DATE: January 29, 2004

INVENTOR-INFORMATION:

NAME CITY STATE COUNTRY RULE-47 Aoki, Kei Roger Coto de Caza CA US Cui, Minglei Irvine CA US Jenkins, Stephen W. Mission Viejo CA US

US-CL-CURRENT: <u>424/239.1</u>

CLAIMS:

We claim:

- 1. A method for treating pain, the method comprising the step of <u>peripheral</u> administration of a <u>neurotoxin</u> to a mammal, wherein the pain treated is not associated with a muscle spasm.
- 2. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ comprises a neuronal binding moiety moiety which is substantially native to the $\underline{\text{neurotoxin}}$.
- 3. The method of claim 1, wherein the neurotoxin is a botulinum toxin..
- 4. The method of claim 1, wherein the <u>neurotoxin is a botulinum toxin</u> elected from the group consisting of <u>botulinum toxin</u> types A, B, C.sub.1, D, E, F and G.
- 5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
- 6. The method of claim 1, wherein the neurotoxin is a modified neurotoxin having at least one amino acid deleted, modified or replaced.
- 7. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is made at least in part by a recombinant process.
- 8. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is administered in an amount between about 0.01 U/kg and about 35 U/kg.
- 9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.
- 10. The method of claim 1, wherein the <u>peripheral</u> administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.

- 11. The method of claim 1, wherein the <u>peripheral</u> administration is carried out subsequent to an onset of a nociceptive event experienced by the mammal.
- 12. A method for alleviating pain, the method comprising the step of <u>peripheral</u> administration of a <u>botulinum toxin</u> to a human patient, thereby alleviating pain, wherein the pain is not associated with a muscle disorder.
- 13. The method of claim 12, wherein the <u>neurotoxin is a botulinum toxin</u> selected from the group consisting of <u>botulinum toxin types A, B, C.sub.1, D, E, F and G.</u>
- 14. A method for treating a pain, the method comprising the step of periph ral administration of a <u>neurotoxin</u> to a mammal, wherein the <u>neurotoxin</u> is a polypeptide comprising: a) a first amino acid sequence region comprising a wild type neuronal binding moiety, substantially completely derived from a <u>neurotoxin</u> selected from a group consisting <u>botulinum toxin</u> types A, B, C.sub.1, D, E, F, G and mixtures thereof; b) a second amino acid sequence region effective to translocate th polypeptide or a part thereof across an endosome membrane; and c) a third amino acid sequence region having therapeutic activity when released into a cytoplasm of a target cell, wherein the pain is not associated with a muscle spasm.
- 15. The method of claim 14, wherein the first amino acid sequence region of the polypeptide comprises a carboxyl terminal of a heavy chain derived from the neurotoxin.
- 16. The method of claim 14, wherein the neurotoxin is botulinum toxin type A.
- 17. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a heavy chain derived from a neurotoxin selected from a group consisting of botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 18. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a <u>toxin</u> heavy chain derived from <u>botulinum</u> toxin type A.
- 19. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a <u>toxin</u> light chain derived from a <u>neurotoxin</u> selected from a group consisting of beratti <u>toxin</u>; butyricum <u>toxin</u>; tetani <u>toxin</u>; botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 20. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from botulinum toxin type A.
- 21. A method for improving patient function, the method comprising the step of peripheral administration of a <a href="mailto:bottle:bottl
- 22. A method for treating post-operative pain, the method comprising the st p of peripheral administration of an effective amount of a botulinum toxin before, during during or immediately after a surgical procedure, thereby alleviating a post-operative pain, wherein the surgical procedure is not carried out to treat a muscle spasm.
- 23. A method for treating a visceral pain the method comprising the step of non-

systemic, local administration of an effective amount of a $\underline{\text{botulinum toxin}}$, thereby alleviating a visceral pain.

- 24. A method for treating pain, the method comprising the step of <u>peripheral</u> administration of a <u>neurotoxin</u> to a mammal, wherein the pain is not substantially due to a muscle spasm.
- 25. The method of claim 24, wherein, the neurotoxin is a botulinum toxin.
- 26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.
- 27. The method of claim 24, wherein the <u>peripheral</u> administration is by subcutaneous administration of the $\underline{neurotoxin}$.

L5: Entry 4 of 14

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TITLE: Methods for treating fibromyalgia

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INVENTOR - INFORMATION:

NAME CITY

STATE COUNTRY RULE-47

Voet, Martin A. San Juan Capistrano

CA US

US-CL-CURRENT: 514/2

CLAIMS:

What is claimed is:

- 1. A method for treating fibromyalgia, the method comprising the step of administering locally a therapeutically effective amount of a <u>Clostridial</u> neurotoxin to a peripheral location of a body of a patient afflicted with fibromyalgia, wherein the <u>peripheral</u> location is not a locus of pain, thereby treating fibromyalgia.
- 2. The method of claim 1 wherein the locus of pain and the <u>peripheral</u> location are located within a same dermatome.
- 3. The method of claim 1 wherein the <u>peripheral</u> location is in a head of the patient, and wherein the locus of pain is not in the head of the patient.
- 4. The method of claim 1 wherein the <u>peripheral</u> location is in a head of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
- 5. The method of claim 1 wherein the <u>peripheral</u> location is in cranial area and/or a a facial area of the patient, and wherein the locus of pain is at a fibromyalgia tender point.
- 6. The method of claim 1 wherein the <u>neurotoxin</u> is selected from the group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F, G, fragments thereof, derivatives thereof, mixtures thereof and combinations thereof.
- 7. The method of claim 1 wherein the <u>neurotoxin</u> is selected from the group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F and G.
- 8. The method of claim 1 wherein the <u>Clostridial neurotoxin is a botulinum neurotoxin</u> type A.
- 9. The method of claim 1 wherein the location of <u>peripheral</u> administration and the locus of pain have neuronal processes that are projected from the same spinal

sensory nerve root.

- 10. The method of claim 1 wherein the <u>Clostridial neurotoxin</u> is administered subcutaneously.
- 11. The method of claim 1 wherein the <u>Clostridial neurotoxin</u> is administered intramuscularly.
- 12. The method of claim 1 wherein the $\underline{Clostridial\ neurotoxin}$ is administered with a needle.
- 13. The method of claim 1 wherein the $\underline{Clostridial\ neurotoxin}$ is administered by needleless injection.
- 14. A method for treating pain, the method comprising the step of administering locally a therapeutically effective amount of a <u>Clostridial neurotoxin to a peripheral</u> location on a body of a patient, wherein the patient has a locus of pain, pain, and wherein the <u>peripheral</u> location is not at the locus of pain, thereby treating the pain.
- 15. The method of claim 14 wherein the locus of pain is at a fibromyalgia tender point.
- 16. The method of claim 15 wherein the patient has at least eleven loci of pain.
- 17. The method of claim 14 wherein the locus of pain and the <u>peripheral</u> location are located within a same dermatome.
- 18. The method of claim 14 wherein the $\underline{\text{neurotoxin}}$ is selected from the group consisting of $\underline{\text{botulinum neurotoxin}}$ types A, B, C, D, E, F, G, fragments thereof, derivatives thereof, mixtures thereof and combinations thereof.
- 19. The method of claim 14 wherein the neurotoxin is selected from the group consisting of bottlinum neurotoxin types A, B, C, D, E, F and G.
- 20. The method of claim 14 wherein the $\underline{\text{Clostridial neurotoxin}}$ is a botulinum $\underline{\text{neurotoxin}}$ type A.
- 21. The method of claim 14 wherein the location of <u>peripheral</u> administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 22. The method of claim 14 wherein the <u>Clostridial neurotoxin</u> is administered subcutaneously.
- 23. The method of claim 14 wherein the $\underline{\text{Clostridial neurotoxin}}$ is administered intramuscularly.
- 24. The method of claim 14 wherein the <u>Clostridial neurotoxin</u> is administered with a needle.
- 25. The method of claim 14 wherein the $\underline{Clostridial\ neurotoxin}$ is administered by needleless injection.
- 26. A method for treating fibromyalgia, the method comprising the step of

administering locally a therapeutically effective amount of a <u>Clostridial neurotoxin</u> neurotoxin to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome substantially encompasses a locus of pain, and wherein the local administration is not at the locus of pain, thereby treating fibromyalgia.

- 27. The method of claim 26 wherein the <u>neurotoxin</u> is selected from the group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F, G, fragments thereof, derivatives thereof, mixtures thereof and combinations thereof.
- 28. The method of claim 26 wherein the <u>neurotoxin</u> is selected from the group consisting of <u>botulinum neurotoxin</u> types A, B, C, D, E, F and G.
- 29. The method of claim 26 wherein the <u>Clostridial neurotoxin is a botulinum</u> neurotoxin type A.
- 30. The method of claim 26 wherein the location of <u>peripheral</u> administration and the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.
- 31. The method of claim 26 wherein the $\underline{\text{Clostridial neurotoxin}}$ is administered subcutaneously.
- 32. The method of claim 26 wherein the $\underline{\text{Clostridial neurotoxin}}$ is administered intramuscularly.
- 33. The method of claim 26 wherein the <u>Clostridial neurotoxin</u> is administered with a needle.
- 34. The method of claim 26 wherein the <u>Clostridial neurotoxin</u> is administered by needleless injection.
- 35. A method for treating pain, the method comprising the step of administering locally a therapeutically effective amount of a <u>Clostridial neurotoxin</u> to a dermatome of a patient, wherein the patient has a locus of pain, wherein the dermatome substantially encompasses the locus of pain, and wherein the local administration is not to the locus of pain, thereby treating the pain.
- 36. The method of claim 35 wherein the locus of pain is at a fibromyalgia tender point.
- 37. The method of claim 36 wherein the patient has at least eleven loci of pain.
- 38. The method of claim 35 wherein the locus of pain and the <u>peripheral</u> location are located within a dermatome.
- 39. The method of claim 35 wherein the $\underline{neurotoxin}$ is selected from the group consisting of $\underline{botulinum\ neurotoxin}$ types A, B, C, D, E, F, G, fragments thereof, derivatives thereof, mixtures thereof and combinations thereof.
- 40. The method of claim 35 wherein the neurotoxin is selected from the group consisting of bottlinum neurotoxin types A, B, C, D, E, F and G.
- 41. The method of claim 35 wherein the Clostridial neurotoxin is a botulinum neurotoxin type A.
- 42. The method of claim 35 wherein the location of peripheral administration and

the locus of pain have neuronal processes that are projected from the same spinal sensory nerve root.

- 43. The method of claim 35 wherein the $\underline{\text{Clostridial neurotoxin}}$ is administered subcutaneously.
- 44. The method of claim 35 wherein the <u>Clostridial neurotoxin</u> is administered intramuscularly.
- 45. The method of claim 35 wherein the <u>Clostridial neurotoxin</u> is administered with a needle.
- 46. The method of claim 35 wherein the $\underline{\text{Clostridial neurotoxin}}$ is administered by needleless injection.
- 47. A method for treating fibromyalgia, the method comprising the step of administering locally a therapeutically effective amount of a <u>botulinum toxin</u> type A to a dermatome of a patient afflicted with fibromyalgia, wherein the dermatome substantially encompasses a locus of pain which is at a fibromyalgia tender point, and wherein the local administration is not at the locus of pain, thereby treating fibromyalgia.
- 48. A method for treating pain, the method comprising the step of administering locally a therapeutically effective amount of a botulinum toxin type A to a dermatome of a patient, wherein the patient has a locus of pain which is at a fibromyalgia tender point, wherein the dermatome substantially encompasses the locus of pain, and wherein the local administration is not to the locus of pain, thereby treating the pain.

L5: Entry 5 of 14

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TITLE: Pain treatment by peripheral administration of a neurotoxin

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INVENTOR-INFORMATION:

NAME CITY STATE COUNTRY RULE-47 Aoki, Kei Roger Coto de Caza CA Cui, Minglei Irvine CA US Jenkins, Stephen W. Mission Viejo CA US

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CLAIMS:

We claim:

- 1. A method for treating pain, the method comprising the step of $\underline{\text{peripheral}}$ administration of a $\underline{\text{neurotoxin}}$ to a mammal, wherein the pain treated is not associated with a muscle spasm.
- 2. The method of claim 1, wherein the $\underline{neurotoxin}$ comprises a neuronal binding moiety moiety which is substantially native to the $\underline{neurotoxin}$.
- 3. The method of claim 1, wherein the neurotoxin is a botulinum toxin.
- 4. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is a botulinum toxin selected from the group consisting of $\underline{\text{botulinum}}$ toxin types A, B, C.sub.1, D, E, F and G.
- 5. The method of claim 1, wherein the neurotoxin is botulinum toxin type A.
- 6. The method of claim 1, wherein the $\underline{neurotoxin}$ is a modified $\underline{neurotoxin}$ having at least one amino acid deleted, modified or replaced.
- 7. The method of claim 1, wherein the $\underline{\text{neurotoxin}}$ is made at least in part by a recombinant process.
- 8. The method of claim 1, wherein the $\underline{neurotoxin}$ is administered in an amount between about 0.01 U/kg and about 35 U/kg.
- 9. The method of claim 1, wherein the pain is substantially alleviated for between about 1 month and about 6 months.
- 10. The method of claim 1, wherein the <u>peripheral</u> administration step is carried out out prior to an onset of a nociceptive event or syndrome experienced by the mammal.

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- 11. The method of claim 1, wherein the <u>peripheral</u> administration is carried out subsequent to an onset of a nociceptive event experienced by the mammal.
- 12. A method for alleviating pain, the method comprising the step of <u>peripheral</u> administration of a <u>botulinum toxin</u> to a human patient, thereby alleviating pain, wherein the pain is not associated with a muscle disorder.
- 13. The method of claim 12, wherein the neurotoxin is a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C.sub.1, D, E, F and G.
- 14. A method for treating a pain, the method comprising the step of <u>peripheral</u> administration of a <u>neurotoxin</u> to a mammal, wherein the <u>neurotoxin</u> is a polypeptide comprising: a) a first amino acid sequence region comprising a wild type neuronal binding moiety, substantially completely derived from a <u>neurotoxin</u> selected from a group consisting <u>botulinum toxin</u> types A, B, C.sub.1, D, E, F, G and mixtures thereof; b) a second amino acid sequence region effective to translocate the polypeptide or a part thereof across an endosome membrane; and c) a third amino acid sequence region having therapeutic activity when released into a cytoplasm of a target cell, wherein the pain is not associated with a muscle spasm.
- 15. The method of claim 14, wherein the first amino acid sequence region of the polypeptide comprises a carboxyl terminal of a heavy chain derived from the neurotoxin.
- 16. The method of claim 14, wherein the neurotoxin is botulinum toxin type A.
- 17. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a heavy chain derived from a neurotoxin selected from a group consisting of botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 18. The method of claim 14, wherein the second amino acid sequence region of the polypeptide comprises an amine terminal of a toxin heavy chain derived from botulinum toxin type A.
- 19. The method of claim 14, wherein the third amino acid sequence region of he polypeptide comprises a <u>toxin</u> light chain derived from a <u>neurotoxin</u> selected from a group consisting of beratti <u>toxin</u>; butyricum <u>toxin</u>; tetani <u>toxin</u>; botulinum toxin types A, B, C.sub.1, D, E, F, G and mixtures thereof.
- 20. The method of claim 14, wherein the third amino acid sequence region of the polypeptide comprises a toxin light chain derived from botulinum toxin type A.
- 21. A method for improving patient function, the method comprising the step of peripheral administration of a botulinum toxin to a patient experiencing a non-muscle disorder related pain, thereby improving patient function as determined by improvement in one or more of the factors of reduced pain, reduced time spent in bed, improve hearing, increased ambulation, healthier attitude and a more varied lifestyle.
- 22. A method for treating post-operative pain, the method comprising the step of peripheral administration of an effective amount of a <u>botulinum toxin</u> before, during during or immediately after a surgical procedure, thereby alleviating a post-operative pain, wherein the surgical procedure is not carried out to treat a muscle spasm.
- 23 A method for treating a visceral pain the method comprising the step of non-

systemic, local administration of an effective amount of a $\underline{\text{botulinum toxin}}$, thereby alleviating a visceral pain.

- 24. A method for treating pain, the method comprising the step of <u>peripheral</u> dministration of a <u>neurotoxin</u> to a mammal, wherein the pain is not substantially due due to a muscle spasm.
- 25. The method of claim 24, wherein, the neurotoxin is a botulinum toxin.
- 26. The method of claim 24, wherein the pain is not secondary to a muscle spasm.
- 27. The method of claim 24, wherein the $\underline{\text{peripheral}}$ administration is by subcutaneous administration of the $\underline{\text{neurotoxin}}$.